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CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8)Applicant(s): **L. Mansfield, M. Rossano, A. Murphy and R. Vrable**

Docket No.

MSU 4.1-458

Application No.

09/513,086

Filing Date

02/24/2000

Examiner

Wu Cheng Winston Shen

Customer No.

21036

Group Art Unit

1632Invention: **VACCINE TO CONTROL EQUINE PROTOZOAL MYELOENCEPHALITIS IN HORSES**I hereby certify that this **SUPPLEMENTAL REPLY IN RESPONSE TO COMMUNICATION***(Identify type of correspondence)*

is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope

addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

July 19, 2007*(Date)***Tammi L. Taylor***(Typed or Printed Name of Person Mailing Correspondence)**Tammi L. Taylor**(Signature of Person Mailing Correspondence)***Note: Each paper must have its own certificate of mailing.**

If any additional fees are required, please charge Deposit Account No. 13-0610.

MSU 4.1-458
Appl. No. 09/513,086
July 13, 2007
Supplemental Reply in Response to Office Communication
mailed June 7, 2007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/513,086 Confirmation No. 4724

Applicants : Linda S. Mansfield, Mary G. Rossano,
Alice J. Murphy, and Ruth A. Vrable

Filed : February 24, 2000

Title: VACCINE TO CONTROL EQUINE PROTOZOAL
MYELOENCEPHALITIS IN HORSES

TC/A.U. : 1632

Examiner : Shen, Wu Cheng Winston

Docket No. : MSU 4.1-458

Customer No. : 21036

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL REPLY IN RESPONSE TO COMMUNICATION

Sir:


In response to the Office Communication mailed June 7, 2007, the Reply Brief indicates that Liang et al., Vol. 66, pages 1834-1838 (1998), paper number 3, page 12 was considered in the prosecution of the above entitled application. Reference to Liang et al. is therefore in

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compliance with 37 CFR 41.41. Attached are copies of the Office Actions cited in the Evidence Appendix. In the Office Action dated January 12, 2006, it is stated that "Examiner agrees that Liang *et al.* provides for the disclosure and use of *Sarcocystis neurona* and not isolated forms of the 16 and 30 kDa proteins. While Liang *et al.* teach a composition that comprises both the 16 and 30 kDa antigen of *S. neurona*, and methods where horses were provided this composition, it fails to anticipate the claims as presently amended". Thus, the Supplemental Reply Brief is not the same as the earlier filed Reply Brief.

A Decision by the Board is requested.

Respectfully,



Ian C. McLeod
Registration No. 20,931

IAN C. McLEOD, P.C.
2190 Commons Parkway
Okemos, MI 48864

Telephone: (517) 347-4100
Facsimile: (517) 347-4103

Attachments: Office Action dated August 16, 2000
Office Action dated January 12, 2006

copy



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/513,086 02/24/00 MANSFIELD L MSU 4.1-458

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MCLEOD & MOYNE
2190 COMMONS PARKWAY
OKEMOS MI 48864

HM22/0816

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AUG 21 2000

IAN C. MCLEOD

EXAMINER

CONNELL, Y

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

READ

AUG 21 2000

IAN C. MCLEOD

*Co. Mansfield
Sherman
8-21-00
N. Hilbert
8-30-00*

*✓ [Signature]
Docketed
Nov 16, 2000 - 3rd me
Feb 16, 2001 - 6th me*

Office Action Summary

Application No.

09/513,086

Applicant(s)

Mansfield et al

Examiner

Yvette Connell Albert

Group Art Unit

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☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) 1-3, 10-12, 18-22, 29-44, 47 and 48 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4-9, 13-17, 23-28, 45, 46, 49, and 50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION IN THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 21-22, drawn to a vaccine comprising antibodies, classified in class 424, subclasses 130.1 and 184.1 .
 - II. Claims 4-9, 13-17, 23-28, 45-46, 49-50, drawn to vaccine comprising antigens, and method of protecting equids via said vaccine, methods of producing polypeptides, classified in class 424, subclass 184.1, class 514, subclass 44, and class 435, subclass 69.1
 - III. Claims 10-12, 18-20, 44-45, 47-50, drawn to vaccine of DNA encoding an antigen, and method of protecting equid against infection via said vaccine, classified in class 424, subclass 185.1 and class 514, subclass 44.
 - IV. Claims 29-35, drawn to methods for producing antibodies, classified in class 435, subclass 70.1.
 - V. Claim 36 , drawn to a monoclonal antibody which selectively binds to antigen, classified in class 530, subclass 387.1.
 - VI. Claim 37, drawn to an isolated recombinant protein, classified in class 530, subclass 350.

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2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are related in that they are all vaccines utilized in protection against infection.

However, the inventions are distinct each from the other as the vaccine of invention I, comprises antibodies, the vaccine of invention II comprises antigens, while the vaccine of invention III comprises DNA encoding an antigen. Additionally, polynucleotides, polypeptides, and antibodies can be used by materially different methods. For example, polynucleotides can be used as hybridization probes for screening cDNA and genomic libraries, polypeptides can be used for antigen presenting cell priming, and antibodies can be used in screening assays. The differences between the inventions are further underscored by their divergent classification and independent search status.

Invention II is related to invention VI as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention VI can be made by another materially different process such as enzymatically or isolated from cells endogenously producing the protein. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

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used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of invention V can be made by another materially different process by isolating from cells endogenously producing the antigen and then using the antigen to make the antibody. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions I-III are distinct from inventions IV-VI since it can be shown that they have different modes of operation, different functions and different effects. The polypeptides are distinct in chemical structure, function as well as therapeutic function from the antibodies, as well as the vaccines which elicit an immune response and provide protection against infection. Furthermore, the inventions of groups II-III involve modifying cellular effects in vivo, requiring different technical considerations and different reagents not involved in the methods and products of the other inventions. The differences between the inventions are further underscored by their divergent classification and independent search status.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and further because the searches required for the different inventions are not coextensive, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ian McCleod on 7/13/00, and again on 7/27/00 a provisional election was made **without** traverse to prosecute the invention of Groups II

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claims 4-9, 13-17, 45-46, 49-50, and Group IV, claims 23-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-3, 10-12, 18-22, 29-44, and 47-48, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4-9, 13-17, 45-46, and 49-50, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Claimed invention. The claims are drawn to a vaccine for active immunization of an equid against a *Sarcocystis neurona* infection comprising at least one epitope of a unique 16+/-4 or

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30+/-4 antigen of said parasite; wherein the antigen is a polypeptide produced in a plasmid in *E. coli*; wherein the antigen is a fusion polypeptide consisting of glutathione S-transferase, protein A, maltose binding protein, and polyhistidine; and provided in a pharmaceutically acceptable carrier. The claims are also drawn to a method for vaccinating an equid against infection via said vaccine and wherein the DNA in the plasmid is operably linked to a promoter which enables transcription; a method of protecting an equid against infection via said vaccine, administered by a vaccination route selected from the group consisting of intranasal, intramuscular administration and intraperitoneal, intradermal, and subcutaneous injection. The claims are further drawn to a method for producing a polypeptide, comprising: providing a microorganism in a culture containing a DNA encoding a fusion polypeptide comprising at least one epitope of a 16 +/-4kDa and/or 30 +/-4kDa antigen of *S. neurona*, and a polypeptide that facilitates isolation of the fusion polypeptide, culturing the microorganism in culture to produce the fusion polypeptide, and isolating the fusion polypeptide.

2. The *in vitro* examples and results on pages 33-44 shows that applicant was successful in preparing monoclonal antibodies which recognize 16+/-4 kDa antigen and/ or 30+/-4 kDa antigen of *Sarcocystis neurona*. Applicant was also successful in preparing a cDNA library which expresses said antigens of *Sarcocystis neurona*; isolating, excystation and culturing *Sarcocystis* species using opossums as a model, and finally, applicant was successful in providing chemical excystation methods for preparing *Sarcocystis* sp. oocysts.

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3. It is not readily apparent that one skilled in the art given applicant's disclosure, would be able to practice the invention over the scope as claimed in view of the lack of guidance provided in the specification as filed.

The specification is not enabling in its disclosure as it fails to teach whether the vaccine for active immunization would in fact induce a protective effect *in vivo*, especially in an equid. Furthermore, the vaccines of the instant invention implies protection of an equid against *S. neurona* infection. The specification does not indicate or demonstrate any *in vivo* results obtained by actively immunizing any host, such that hosts if and when challenged, said hosts would be protected from developing an infection due to *S. neurona*. In addition, the specification fails to teach the correlation between the *in vitro* results shown and *in vivo* protection of any hosts against *S. neurona* infection, by the vaccine composition of the present invention. Therefore, the specification appears to be wholly prophetic in its vaccine composition and methods of conferring protection via said vaccine to equids, against *S. neurona* infection.

4. The physiological art of utilizing a vaccine for active immunization of equids against *Sarcocystis neurona* infection at the time of the invention would have been considered unpredictable. According to Kisthardt et al, 1997, vaccination of horses against *S. neurona* infection would aid in the prevention of EPM or equine protozoal myeloencephalitis, but currently, no vaccines are available. Once the horse/opossum life cycle is confirmed and reproduced experimentally then the development of effective vaccines should follow(Kisthardt, see page 13 1st para).

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Furthermore, Liang et al, 1998, states that although no successful vaccine against related apicomplexan parasites has been widely used, there are encouraging signs that such a vaccine is possible(Liang, see page 1834, left col, 2nd para). In addition, CSF or cerebrospinal fluid samples with different immunoblot band patterns strongly suggest that antibodies specific for Sn 14 and Sn 16 have protective activity against *S. neurona*, at least in vitro, while antibodies to Sn 30 are not recognized as specific since a 30 kDa antigen immunoreactive with sera from horses with EPM is found in other *Sarcocystis* spp(Liang, see page 1837, left col, 1st para). . . *S. neurona* infection of the horse induces production of antibodies to Sn 14 and Sn 16, indicating that these two proteins are expressed in vivo and are strong immunogens in the horse, and as such they warrant further investigation as candidate antigens for inclusion in vaccines against *S. neurona* infection(Liang, see page 1837, right col, last para).

5. In the absence of specific guidance which is lacking in the specification as filed and given the state of the art at the time of filing, coupled with the reasons discussed above, it would require undue experimentation for one skilled in the art to practice the methods or use the claimed products as disclosed in the specification.

The quantity of experimentation required to practice the invention as claimed would require the identification of the specific surface antigens, Sn 16 and Sn 30, from a parasite [*S. neurona*] which may express different proteins at different stages of *in vivo* or *in vitro* development, some proteins may be expressed and function essentially only *in vitro*, and such proteins would be inappropriate targets for vaccine development(Liang et al, see page 1837, last

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para). Therefore, it would require undue experimentation to identify and isolate specific surface antigens which would be effective both *in vitro* and *in vivo*, especially in the absence of an *in vivo* model, in protecting against *S. neurona* infection. This is considered trial and error experimentation and as such is considered undue.

5. Claims 23-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a polypeptide comprising providing *Sarcocystis neurona* in a culture containing a DNA encoding a fusion polypeptide comprising at least one epitope of a 16 +/- 4 and /or 30 +/- 4 kDa antigens of *Sarcocystis neurona* and a polypeptide that facilitates isolation of the fusion polypeptide; culturing the microorganism in a culture to produce the fusion polypeptide and isolating the fusion polypeptide, does not reasonably provide enablement for any method of producing any polypeptide comprising providing any microorganism containing any DNA encoding any fusion polypeptide comprising at least one epitope of a 16 +/- 4 and /or 30 +/- 4 kDa antigens of *Sarcocystis neurona* and any polypeptide that facilitates isolation of the fusion polypeptide; culturing the microorganism in any culture to produce the fusion polypeptide and isolating the fusion polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

1. Claimed invention. The claims are drawn to a method for producing a polypeptide by providing a microorganism containing a DNA encoding a fusion polypeptide comprising at least

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one epitope of a 16 +/- 4 and /or 30 +/- 4 kDa antigens of *Sarcocystis neurona* and a polypeptide that facilitates isolation of the fusion polypeptide; culturing the microorganism in any culture to produce the fusion polypeptide and isolating the fusion polypeptide. The claims are also drawn to said method for producing a polypeptide wherein isolating the fusion polypeptide is by affinity chromatography; and wherein the polypeptide is all or a portion of protein A and the affinity chromatography comprises an IgG-linked resin; wherein the polypeptide is polyhistidine and the affinity chromatography comprises a Ni²⁺ resin; wherein the polypeptide is glutathione S-transferase and the affinity chromatography comprises a glutathione Sepharose 4B resin; and wherein the polypeptide is maltose binding protein and the affinity chromatography comprises an amylose resin.

2. The *in vitro* examples and results on pages 33-44 shows that applicant was successful in preparing monoclonal antibodies which recognize 16+/-4 kDa antigen and/ or 30+/-4 kDa antigen of *Sarcocystis neurona*. Applicant was also successful in preparing a cDNA library which expresses said antigens of *Sarcocystis neurona*; isolating, excystation and culturing *Sarcocystis* species using opossums as a model, and finally, applicant was successful in providing chemical excystation methods for preparing *Sarcocystis* sp. oocysts.

3. It is not readily apparent that one skilled in the art given applicant's disclosure, would be able to practice the invention over the scope as claimed in view of the lack of guidance provided in the specification as filed.

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The specification is not enabling in its disclosure as it fails to teach a specific or preferred expression system, whether bacterial or eukaryotic expression system, for producing the antigens of the present invention.

4. The physiological art of producing polypeptides by providing microorganisms in culture containing DNA encoding a fusion polypeptide and polypeptide which facilitates isolation of the fusion polypeptide, culturing the microorganism in a culture to produce the fusion polypeptide and isolating the fusion polypeptide, at the time of the invention was well established and yielded excellent results by those skilled in the art.

5. In the absence of specific guidance which is lacking in the specification as filed, and given the state of the art at the time of filing, coupled with the reasons discussed above, it would require undue experimentation for one skilled in the art to practice the methods or use the claimed products as disclosed in the specification.

The quantity of experimentation required to practice the invention as claimed would require one to select a microorganism in a specified culture medium, containing DNA encoding a fusion polypeptide comprising an antigen of S. neurona, and a polypeptide which facilitates isolation of the fusion polypeptide; culturing the microorganism in a culture to produce the fusion polypeptide and isolating the fusion polypeptide. This is trial and error experimentation as one must select any microorganism from any source or origin, bacterial or eukaryotic, which contains a DNA encoding a fusion polypeptide which comprises at least one epitope of said Sn antigen, which when combined with another polypeptide would facilitate the isolation of the fusion

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polypeptide. There are innumerable permutations associated with this experiment as one must decide which specific microorganism with which DNA encoding fusion polypeptide, and in the present of which other polypeptide would result in the desired product. In the absence of specific guidance, this is considered an invitation to experimentation and as such is considered undue.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Liang et al, 1998.

Applicant's claims are essentially directed to a composition comprising at least one epitope of a unique 16 +/- 4 antigen of *Sarcocystis neurona*.

Liang et al teaches that *S. neurona* surface proteins Sn 14 and Sn 16 kDa, were isolated by a combination of surface protein labeling, immunoprecipitation and Western blotting(see page 1836, left col, 1st para), which could be useful as components of a vaccine against *S. neurona* infection(see abstract).

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Therefore, the claimed invention was anticipated by Liang et al who taught at least one epitope of a unique 16 +/- 4 antigen of *Sarcocystis neurona* in isolation, and which could be used in vaccine compositions.

Claims 5-9, 13-17, 23-28, 45-46, and 49-50 are free of the prior art. However, the closest related prior art to Liang et al, 1998, teaches *S. neurona* surface proteins Sn 14 and Sn 16 may be useful components of a vaccine against *S. neurona* infection, but does not teach surface protein Sn 30, or a method for producing a polypeptide, comprising: providing a microorganism in a culture containing a DNA encoding a fusion polypeptide comprising at least one epitope of a 16 +/-4kDa and/or 30 +/-4kDa antigen of *S. neurona*, and a polypeptide that facilitates isolation of the fusion polypeptide, culturing the microorganism in culture to produce the fusion polypeptide, and isolating the fusion polypeptide, as broadly claimed.

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Conclusion

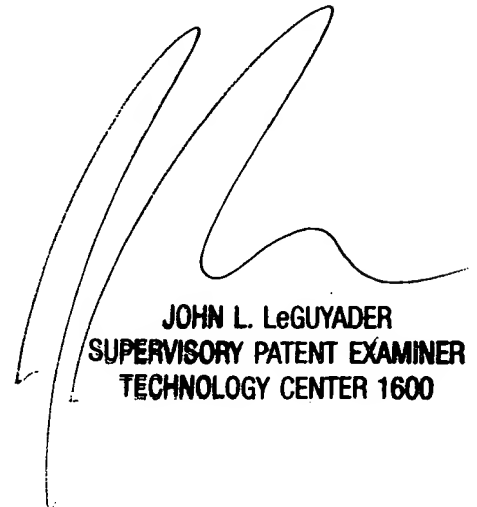
No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvette Connell, whose telephone number is 703-308-7942. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447.

Any inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Yvette Connell

July 31, 2000



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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PTO/SB/08A (10-96)

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
		Application Number			
		Filing Date			
		First Named Inventor		Linda S. Mansfield	
		Group Art Unit			
		Examiner Name			
Sheet 2 of 2		Attorney Docket Number		MSU 4.1-458	

U.S. PATENT DOCUMENTS						
Examiner Initials [*]	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
8	AU	5,580,859		Felgner	12/1996	
	AV	5,561,064		Marquet et al	10/1996	
	AW	5,977,322		Marks et al	11/1999	
	AX	5,693,762		Queen et al	12/1997	
	AY	5,693,761		Queen et al	12/1997	
	AZ	5,620,845		Gould et al	4/1997	
	BA	5,559,041		Kang et al	9/1996	
	BB	5,656,448		Kang et al	8/1997	
	BC	5,728,587		Kang et al	3/1998	
	BD	5,695,928		Stewart	12/1997	
	BE	5,169,789		Bernstein	12/1992	
	BF	4,486,530		David et al	12/1984	
	BG	4,786,589		Rounds	11/1988	

FOREIGN PATENT DOCUMENTS								
Examiner Initials [*]	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

Examiner Signature: YUETIE CORNEL	Date Considered: 7/17/00
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	
				Filing Date	
				First Named Inventor Linda S. Mansfield	
				Group Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket Number MSU 4.1-458	

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
8	AA	5,935,591		Rossignol et al	8/1999	
	AB	4,883,095		Granstrom et al	3/1999	
	AC	5,830,893		Russell	11/1998	
	AD	4,747,476		Russell	5/1998	
	AE	5,925,622		Rossignol et al	7/1999	
	AF	5,725,863		Daniels et al	3/1998	
	AG	5,585,100		Mond et al	12/1996	
	AH	5,589,384		Liscombe	12/1996	
	AI	5,229,293		Matsuura et al	7/1993	
	AJ	5,223,424		Cochran et al	6/1993	
	AK	5,338,683		Paoletti	8/1994	
	AL	5,494,807		Paoletti et al	2/1996	
	AM	5,935,777		Moyer et al	8/1999	
	AN	5,928,913		Efstathiou et al	7/1999	
	AO	5,741,696		Cochran et al	4/1998	
	AP	5,731,188		Cochran et al	3/1998	
	AQ	5,266,313		Esposito et al	11/1993	
	AR	5,800,821		Acheson et al	9/1998	
	AS	5,703,055		Felgner	12/1997	
8	AT	5,589,466		Felgner	12/1996	

FOREIGN PATENT DOCUMENTS								
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
		Office ³	Number ⁴	Kind Code ² (if known)				

Examiner Signature	YUETTE CONNELL	Date Considered	7/17/00
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number		
			Filing Date		
			First Named Inventor	Linda S. Mansfield	
			Group Art Unit		
			Examiner Name		
Sheet	1	of	2	Attorney Docket Number	MSU 4.1-458

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Q	A	McKay et al., Veterinary Clinics of North America: Equine Practice for Practicing Vets. 13(1):79-96 (1997)	
	B	Blythe et al., J. Am. Vet. Med. Assoc. 210: 525-527 (1997).	
	C	Saville et al., J. Am. Vet. Assoc. 210: 519-524 (1997).	
	D	Bentz et al., J. Am. Vet. Med. Assoc. 210: 517-518 (1997).	
	E	Granstom et al., J. Vet. Diag. Invest. 5: 88-90 (1993).	
	F	Fenger et al., Vet. Parasitol. 68: 199-213 (1997).	
	G	Martenuik et al., Proceedings of the Conference of Research Workers in Animal Diseases, Chicago, IL (1997).	
	H	Motin et al., Infect. Immun. 64: 4313-4318 (1996).	
J	I	Motin et al., Infect. Immun. 64: 3021-3029 (1995).	
	J	Molecular Cloning: A Laboratory Manual, Second Ed. edited by Sambrook et al. Cold Spring Harbor Lab. Press, Cold Spring Harbor, New York (1989).	
R	K	Engvall et al., Immunochem. 8: 871 (1971).	

Examiner Signature	YVETTE CONNELL	Date Considered	7/17/00
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¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			<i>Complete if Known</i>		
			Application Number		
			Filing Date		
			First Named Inventor	Linda S. Mansfield	
			Group Art Unit		
			Examiner Name		
Sheet	2	of	2	Attorney Docket Number	MSU 4.1-458

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Ⓟ	L	Ljunggren et al., J. Immunol. Methods 104: 7-14 (1987).	
	M	Kemeny et al., J. Immunol. Methods 87: 45-50 (1986).	
	N	Antibodies, A Laboratory Manual, eds. Harlow and Lane, Cold Spring Harbor Lab. Press, Cold Spring Harbor, New York, (1988).	
	O	Sloss et al., In Veterinary Clinical Parasitology, Iowa State Univ. Press, Ames, Iowa, (1994) p. 198	
	P	Marsh et al., J. Parasitology 83: 1189-1192 (1997).	
Ⓟ	Q	Speer et al., J. Protozoology 33: 486-490 (1986).	

Examiner Signature	YUETTE CONNELL	Date Considered	7/17/00
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Notice of References Cited				Application No. 9/513,086		Applicant(s) Mansfield et al	
				Examiner Yvette Connell Albert		Group Art Unit 1633	

U.S. PATENT DOCUMENTS							
	DOCUMENT NO.	DATE		NAME	CLASS	SUBCLASS	
A							
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY		NAME	CLASS	SUBCLASS
N							
O							
P							
Q							
R							
S							
T							

NON-PATENT DOCUMENTS		
	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U	Liang et al. Evidence that surface proteins Sn 14 and Sn 15 of Sarcocystis neurona merozoites are involved in infection and immunity. Infection and immunity. Vol. 66, No. 5, pgs. 1834-1838, 1998.	1998
V	Kisthardt, et al. Equine protozoal myeloencephalitis. Equine Practice, Vol. 19, No. 2, pgs. 8-13, 1997.	1997
W		
X		



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/513,086

02/24/2000

Linda S. Mansfield

MSU 4.1-458

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01/12/2006

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2190 COMMONS PARKWAY
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RECEIVED

JAN 13 2006

IAN C. McLEOD

EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

READ

JAN 13 2006

Ian C. McLeod

*Linda S. Mansfield
& Hudson
1/2/06*

*Approved
Black Ted
Mar. 12, 2006 - 2nd mo
Apr. 12, 2006 - 3rd mo
July 12, 2006 - 6th mo.*

Office Action Summary	Application No. 09/513,086	Applicant(s) MANSFIELD ET AL.	
	Examiner Joseph T. Voitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 11, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 13, 46 and 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 13, 46 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2005 has been entered.

DETAILED ACTION

This application filed February 24, 2000, claims benefit to provisional application 60/152,193, filed September 2, 1999.

Applicants amendment filed October 28, 2005, has been received and entered. Claims 1-3, 5-12, 14-45, 47-49 have been canceled. Claims 4, 13, 46 and 50 have been amended. Claims 4, 13, 46 and 50 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended claims 4, 13 and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Applicants indicate that the prior office action suggested "naturally occurring" protein antigens (amendment page 5, Remarks section), however Examiner can not find this suggestion within the last office action. More importantly, Applicants do not point to support in the specification for the new amendments and in a review of the present specification Examiner can not find support for the instant claim amendments. It appears that the specification would support *inter alia* "consisting" since it does contemplate the two proteins in a composition (for example page 5, lines 1-12). However, the only support for "isolated" is in the context of a recombinant protein (page 9, lines 5-21). Further, there is no literal support for isolating the 16 and 30 kDa proteins directly from *Sarcocystis neurona* as a contemplated part of the invention. To the contrary, a review of the summary of the invention focuses on providing only recombinant proteins in the form of a fusion protein for isolation, as well as using DNA that can encode said fusion proteins, and provides no basis for the present invention to be an isolated protein from *Sarcocystis neurona*. In addition, there does not appear to be support for "naturally occurring" in the context of the claim. While it would not be contested that such forms of the protein exist in nature, the literal support for this embodiment can not be found, in particular in the context of an "antigen" versus the protein itself that exists in nature. Importantly, it would imply non-naturally occurring forms of the protein/antigen which is supported by the present specification at best in the context of a recombinant protein not in the embodiment that some sort of variants of the 16 and 30 kDa proteins were previously encompassed by the claims and taught by the present specification.

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To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 4, 13 and 46 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claims 4, 13, 46 and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants note the amendment to the claims, in particular the addition of language that clarify that the composition "consisting of" (no longer "comprising of") and that it is an isolated protein antigen (page 5), and argue that the 16 and 30 kDa proteins are described by their physical properties including a source of the material, not merely by function (page 6).

Applicants point to example 1 in the specification for exemplification of a 2-D gel separation of the protein, and use for generating monoclonal antibodies (page 7) and argue that one of ordinary skill in the art could perform such techniques and obtain isolated forms of the 16 and 30 kDa proteins (page 8). See Applicants' amendment pages 5-8. Applicants arguments have been fully considered, but not found persuasive.

As noted in the final office action, Examiner acknowledges that Example 1 provides general methodology for two dimensional gel electrophoresis and even without this teaching one of skill in the art would be able to obtain both 16 and 30 kDa proteins from *S. neurona*. Examiner agrees that methods of electrophoresis and immuno-assays are well known in the art, however this is insufficient to describe relevant structural and functional elements of the claimed product, nor does it provide any guidance to the antigens nor antigenic fragments would provide a form of treatment in the claimed methodology of treating equine. The amendment to the claims are noted (and beyond the new matter rejection set forth above) as indicated in the final office action "at issue is whether the specification even meets the requirements of 35 USC 112, first paragraph, for the isolated forms of the naturally occurring proteins" (see page 3 of the final office action mailed 7/11/2005). Again, a search of the relevant art for disclosure of the specific

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sequences instantly claimed indicate that this is still a subject of research, and that new isolates provide further evidence that variants of the specific sequence are present in nature (see for example Hyun *et al.* Vet Parasitol. 2003 Feb 28;112(1-2):11-20, Sequence comparison of *Sarcocystis neurona* surface antigen from multiple isolates).

Most simply put would be an example where a specific sequence is disclosed and whether the present disclosure provides sufficient description for the skilled artisan to recognize that the sequence was specifically contemplated as the invention. For example, Ellison *et al.* (Int J Parasitol. 2002 Feb;32(2):217-25) Molecular characterization of a major 29 kDa surface antigen of *Sarcocystis neurona*) teaches a protein that meets the size requirements of the protein in the claimed composition, but given the present disclosure clearly the specific sequence of Ellison *et al.* would not have been predicted or even obvious given the present specification. Case law has established that one cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. Importantly, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, for the reasons above and of record it is maintained that

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the polypeptide sequences needed to make and use the claimed invention do meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 13 and 46 rejected under 35 U.S.C. 102(b) as being anticipated by Liang *et al.*
is withdrawn.

Examiner agrees that Liang *et al.* provides for the disclosure and use of *Sarcocystis neurona* and not isolated forms of the 16 and 30 kDa proteins. While Liang *et al.* teach a composition that comprises both the 16 and 30 kDa antigen of *S. neurona*, and methods where horses were provided this composition, it fails to anticipate the claims as presently amended.

See also Applicants' amendment, pages 8-13.

Conclusion

No claim is allowed.

It is noted that related application 09/670,355, which is a divisional of the present application and has the same specification, thus provides the same guidance and level of enablement as the present specification, has been abandoned after the BPAI affirming similar rejections as set forth above. It is noted that '355 was directed to polynucleotides and the present

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claims are directed to polypeptides, however the Board recognized that neither the present specification nor the prior art provides the necessary guidance and description to either the nucleic acid or the protein (page 5 of the decision mailed September 30, 2004), affirming the written description and enablement rejections of the Office.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

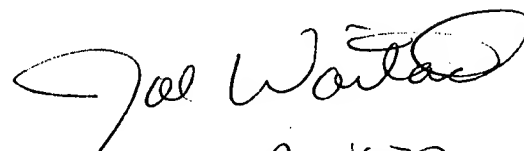
Application/Control Number: 09/513,086

Page 9

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach


A-1632